

E UNITED STATES PATENT AND TRADEMARK OFFICE

\$

Group Art Unit: 1616

Attorney

Docket: 26682

In re Applicant: Alexander LEVITZKI, et al

Serial No.: 10/659,747

Filed: 11 September 2003

For: RADIOLABELED IRREVERSIBLE

INHIBITORS OF EPIDERMAL

GROWTH FACTOR RECEPTOR...

Examiner:

Commissioner for Patents PO Box 1450

Alexandria, VA 22313-1450

RENEWED REQUEST FOR CORRECTED FILING RECEIPT

Sir:

Attached is a copy of the official filing receipt received from the United States Patent and Trademark Office in the above application. Issuance of a corrected filing receipt to correct an error of the USPTO is respectfully requested.

In "Domestic Priority data as claimed by applicant", please add the reference 09/802,928 03/12/2001.

A copy of the first paragraph of the Specification showing the aforesaid application being claimed is attached hereto.

Respectfully submitted,

Registration No. 25,457

Date: January 9, 2005

APPLICATION FOR PATENT

Inventors: Alexander Levitzki, Eyal Mishani, Giuseppina Ortu, Iris Ben

David and Yulia Rozen

5

10

15

20

25

30

35

Title: RADIOLABELED IRREVERSIBLE INHIBITORS OF

EPIDERMAL GROWTH FACTOR RECEPTOR TYROSINE

KINASE AND THEIR USE IN RADIOIMAGING AND

RADIOTHERAPY

This is a continuation-in-part of PCT/IL02/00199, filed March 12, 2002, which claims priority from U.S. Patent application No. 09/802,928, filed March 12, 2001, now U.S. Patent No. 6,562,319, issued May 13, 2003.

FIELD AND BACKGROUND OF THE INVENTION

The present invention relates to radiolabeled compounds and their use in radioimaging and/or radiotherapy. More particularly, the present invention relates to radiolabeled irreversible inhibitors of epidermal growth factor receptor tyrosine kinase (EGFR-TK) and their use as biomarkers for medicinal radioimaging such as Positron Emission Tomography (PET) and Single Photon Emission Computed Tomography (SPECT), and as radiopharmaceuticals for radiotherapy.

The use of radioactive nuclides for medicinal purposes is well known in the art. Biologically active compounds that bind to specific cell surface receptors or that in other ways modify cellular functions have received some consideration as radiopharmaceuticals, and therefore, when labeled with a radioactive nuclide, such compounds are used as biospecific agents in radioimaging and radiotherapy.

Positron Emission Tomography (PET), a nuclear medicine imagine technology which allows the three-dimensional, quantitative determination of the distribution of radioactivity within the human body, is becoming an increasingly important tool for the measurement of physiological, biochemical,







APPLICATION NUMBER

FILING OR 371(c) DATE

FIRST NAMED APPLICANT

ATTY. DOCKET NO./TITLE

10/659,747

09/11/2003

Alexander Levitzki

26682

CONFIRMATION NO. 3467

G.E. EHRLICH (1995) LTD. c/o ANTHONY CASTORINA **SUITE 207** 2001 JEFFERSON DAVIS HIGHWAY **ARLINGTON, VA 22202**

OC000000014698385

Date Mailed: 12/08/2004

RESPONSE TO REQUEST FOR CORRECTED FILING RECEIPT

Domestic Continuity and Foreign Priority

In response to your request for a corrected Filing Receipt, the Office is unable to comply with the request because:

The priority or continuity claim has not been entered because it was not filed during the required time period. Applicant may wish to consider filing a petition to accept an unintentionally delayed claim for priority. See 37 CFR 1.55 or 1.78.
Continuity claimed under 35 U.S.C. § 120 cannot be added to the Filing Receipt without the applicant supplying the relationship (continuation, divisional, or continuation-in-part) in an Application Data Sheet or amendment to the first page of the specification. 09/1802,928
A claim for priority cannot be made based on an application filed after the application making the claim.
Domestic benefit and foreign priority claims will not be captured in a provisional application. A provisional application is not entitled to a right of priority or to the benefit of an earlier filing date of any other application. See 35 U.S.C. § 111(b)(7) and 37 CFR 1.53(c)(4).
A domestic continuity claim cannot be made to a foreign application and the filing receipt will only list the foreign country, application number, and filing date.
 Foreign priority will appear on the Filing Receipt in the following order: Country, Application number, Filing date.
This application is the result of a conversion from a provisional application. Priority based on such

	The application(s) to which priority is claimed were filed over a year prior to the filing date of this application. Therefore, the referenced application(s) cannot be claimed as domestic or foreign priority.
	To change the benefit claim of a U.S. prior-filed application, applicant must amend the first sentence of the specification (if the benefit claim is referenced in the specification), or provide a supplemental application data sheet (ADS) (if the benefit claim was submitted in an ADS), with the desired benefit claim. Note that once a benefit claim is deleted, applicant will not be able to claim such prior-filed application again, if the above-identified application was filed on or after November 29, 2000.
	To change a foreign priority claim, applicant must submit a supplemental oath or declaration (if the priority claim is referenced in the oath or declaration), or a supplemental application data sheet (ADS) (if the priority claim was submitted in an ADS), with the desired priority claim. If a supplemental ADS is submitted, any deletions should be shown with strikeouts. Note that once a priority claim is deleted, applicant will not be able to claim such foreign application again, if the above-identified application was filed on or after November 29, 2000.
Q.C.	Service Center
	nt Examination Division (703) 308-1202
	PART 1 - ATTORNEY/APPLICANT COPY

4





United States Patent and Trademark Office

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS

P.O. Box 1450 Alexandria, Vinginia 22313-1450 www.usplo.gov

FILING OR 371 APPL NO. **ART UNIT** FIL FEE REC'D ATTY.DOCKET NO DRAWINGS TOT CLMS IND CLMS (c) DATE 10/659.747 09/11/2003 1616 0.00 26682 93 5

CONFIRMATION NO. 3467

FILING RECEIPT

*OC000000012568197

G.E. EHRLICH (1995) LTD. c/o ANTHONY CASTORINA **SUITE 207** 2001 JEFFERSON DAVIS HIGHWAY ARLINGTON, VA 22202

Date Mailed: 05/07/2004

Receipt is acknowledged of this regular Patent Application. It will be considered in its order and you will be notified as to the results of the examination. Be sure to provide the U.S. APPLICATION NUMBER, FILING DATE, NAME OF APPLICANT, and TITLE OF INVENTION when inquiring about this application. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this receipt. If an error is noted on this Filing Receipt, please write to the Office of Initial Patent Examination's Filing Receipt Corrections, facsimile number 703-746-9195. Please provide a copy of this Filing Receipt with the changes noted thereon. If you received a "Notice to File Missing Parts" for this application, please submit any corrections to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections (if appropriate).

Applicant(s)

Alexander Levitzki, Jerusalem, ISRAEL; Eyal Mishani, Mevaseret Zion, ISRAEL: Giuseppina Ortu, Jerusalem, ISRAEL: Iris Ben-David, Ashdod, ISRAEL; Yulia Rozen, Jerusalem, ISRAEL;

Domestic Priority data as claimed by applicant

This application is a CIP of PCT/IL02/00199 03/12/2002

Foreign Applications

If Required, Foreign Filing License Granted: 05/07/2004

Projected Publication Date: To Be Determined - pending completion of Missing Parts

Non-Publication Request: No

Early Publication Request: No

** SMALL ENTITY **

Title

Radiolabeled irreversible inhibitors of epidermal growth factor receptor tyrosine kinase and their use in radioimaging and radiotherapy

Preliminary Class

424

LICENSE FOR FOREIGN FILING UNDER Title 35, United States Code, Section 184 Title 37, Code of Federal Regulations, 5.11 & 5.15

GRANTED

The applicant has been granted a license under 35 U.S.C. 184, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" followed by a date appears on this form. Such licenses are issued in all applications where the conditions for issuance of a license have been met, regardless of whether or not a license may be required as set forth in 37 CFR 5.15. The scope and limitations of this license are set forth in 37 CFR 5.15(a) unless an earlier license has been issued under 37 CFR 5.15(b). The license is subject to revocation upon written notification. The date indicated is the effective date of the license, unless an earlier license of similar scope has been granted under 37 CFR 5.13 or 5.14.

This license is to be retained by the licensee and may be used at any time on or after the effective date thereof unless it is revoked. This license is automatically transferred to any related applications(s) filed under 37 CFR 1.53(d). This license is not retroactive.

The grant of a license does not in any way lessen the responsibility of a licensee for the security of the subject matter as imposed by any Government contract or the provisions of existing laws relating to espionage and the national security or the export of technical data. Licensees should apprise themselves of current regulations especially with respect to certain countries, of other agencies, particularly the Office of Defense Trade Controls, Department of State (with respect to Arms, Munitions and Implements of War (22 CFR 121-128)); the Office of Export Administration, Department of Commerce (15 CFR 370.10 (j)); the Office of Foreign Assets Control, Department of Treasury (31 CFR Parts 500+) and the Department of Energy.

NOT GRANTED

No license under 35 U.S.C. 184 has been granted at this time, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" DOES NOT appear on this form. Applicant may still petition for a license under 37 CFR 5.12, if a license is desired before the expiration of 6 months from the filing date of the application. If 6 months has lapsed from the filing date of this application and the licensee has not received any indication of a secrecy order under 35 U.S.C. 181, the licensee may foreign file the application pursuant to 37 CFR 5.15(b).